

Appl. No.: 10/623,271
Amendment Dated: August 24, 2005
Reply to Office Action of March 24, 2005

Amendments to the Specification:

Please replace paragraph on page 9, lines 14-21, with the following amended paragraph:

Figure 2 shows the interior surface 59 of the elongated support member 11 is lined with at least one or more support pad(s) 12 attached therein. The support pad(s) 12 and internal pad 35 may be fastened to the interior surface 59 by, but not limited to, hook and loop material such as Velcro™, adhesive, pins, screws, buttons and the like. The support pad(s) 12 may contour a substantial portion or entire surface area of the interior surface 59. In the most preferred embodiment, ~~at least one~~ of the support pads 12 has a tongue which projects beyond the surface area of the interior surface 59 and is designed to extend around the volar surface of the radius-ulna region.

Please replace paragraph beginning on page 9, lines 22-24, and ending on page 10, lines 1-6, with the following amended paragraph:

At least one releasable fastener 1415 is coupled to the exterior surface 57 of the elongated support member 11, preferably on the middle region 53 as depicted in Figures 3, 5 and 6. The releasable fastener 15, preferably a strap, may be fastened to the exterior surface 57 by, but not limited to, Velcro™, adhesive, pins, screws, buttons, nuts, bolts and the like. Specifically, a first end of the releasable fastener 15 is mounted, preferably to a hook and loop patch 14 adhered onto the exterior surface 57 of the support member 11. A second end of

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the releasable fastener 15 orthogonally extends from the exterior surface 57 and is attached to the tongue of the support pad 12.

Please replace paragraphs on page 10, lines 12-23, with the following amended paragraphs:

The distal end 50 has opposing sides 70, 72, where each side includes an aperture 16 bored through the support member 11 and capable of receiving connectors 90[[30]] therein. Each aperture 16 has a reinforcement perpendicularly extending therefrom designed to surround and support the connectors 90 inserted through the apertures 16.

The hinge system 20 comprises a shell 21 having polar extended sides 22, 23 and a lip 24. An interior pad 35[[26]] is removably attached underneath the polar extended sides 22, 23 thereby providing comfort to the carpal region of the user. Each polar extended side 22, 23 has an aperture 28 capable of accepting fasteners therein. These apertures 28 directly correspond to and are positioned underneath the apertures 16 of the support member 11 in order to accept the inserted connectors 90.

Please replace paragraphs on page 11, lines 6-21, with the following amended paragraphs:

Operatively speaking, the joint may be flexed at about a 150° angle in a downward manner only limited by the user's natural range of motion. In an alternative embodiment, ~~then the~~ angle of the articulated joint may be severely limited by incorporating stops 120 on both the shell 21 and the support member 11 to limit extension, flexion and ulnar-radial deviation. As each stop abuts one another, the range of motion is inhibited.

The orthotic protective device 5 undergoes a scanning and molding process, namely by first scanning and measuring a user's physiological specifications; and then translating the measurements into a mold. The mold is then fabricated by utilizing a wet lay-up process using a combination of epoxy resin, carbon fiber and Kevlar composite materials. This process allows for normal movement of the carpal region. The resulting protective device 5 is designed to limit both extension and flexion of the carpal region specific to the patient's maximum range of motion. Further, during the scanning, molding and fabrication process, the stops 120 are formed onto the shell 21 and the support member 11 thereby limiting the user's movement, both natural and hyperextended/hyperflexed movements[[.]], as shown in Figure 8.

Please replace paragraphs beginning on page 12, lines 1-24, and ending on page 13 at line 15, with the following amended paragraphs:

The metacarpal unit 30 incorporates a casing 31 including an internal surface 33[[50]], and an external surface 51 having an anterior end [[52]]and a posterior end[[54]]. An internal pad 35 has a tongue 100 and is removably connected to the internal surface 33[[50]] of the casing 31, preferably by a hook and loop means. Here, either a hook or loop patch is fastened to the internal surface 33[[50]] and is adapted to accept the internal pad 35 as the loop or hook, respectively, are mated. The internal pad 35 substantially conforms to the surface area of the internal surface 33[[50]] and the tongue 100 projects outwardly and is designed to extend around the volar surface of the user's palm. The tongue 100 has a digit, namely a thumb, orifice 110 allowing the digit to be inserted therethrough.

A first end of an attachment means 32, namely a strap, is fastened to the casing 31, preferably by a hook and loop connector 34 being adhered to the external surface 51 of the casing 31. The attachment means 32 has the corresponding loop or hook patch, respectively, used to join to the former patch. A second end extends transversely across the external surface and orthogonally extends from the external surface 51 of the casing 31 and is attached to the tongue 100 of the internal pad 35.

Each pad, namely the support pad(s) 12, interior pad 35[[26]] and internal pad 35 are resistently compressible, high surface-friction pads designed to

secure the orthotic protective device 5 to the user. The pads 12[[, 26]] and 35 may be made from such materials as, but not limited to, open cell foam, closed cell foam, viscoelastic polymer-gel, cotton, liquid material, granular material or air material. In the most preferred embodiment, each pad 12[[, 26,]] and 35 may include cooling and/or heating coils [[42]] embedded within each pad 12[[, 26,]] and 35 to either provide the user a cooling or heated effect to reduce swelling and provide relief. These coils [[42]] are electrically connected to a temperature control means [[40]] which may be manipulated by the user to produce a desired effect.

The posterior end [[54]] of the casing 31 has an aperture 58 which corresponds to the aperture 28 located on the lip 24 of the shell 21. The swivel joint 95 or other connector is accepted by both apertures 28, 58 alike and provides for the metacarpal unit 30 to move in a lateral fashion with respect to the hinge system 20. Specifically, the swivel joint 95 allows up to a 60° turn on each side of its horizontal axis providing for normal movement of the carpal region. In a preferred embodiment, the swivel joint 95, as well as the connectors 90 may comprise of quick release pins allowing for each addition or subtraction of either the base unit [[16]]10, metacarpal unit 30 or other accessory or accessories adapted to fit thereto. Further, in a preferred embodiment, the casing 31 and the shell 21 may be made of such materials as, but not limited to, moldable carbon fiber, epoxy matrix carbon fiber, Kevlar composite material,

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hard plastic or thermoplastic material which either being mass produced or having a more customized fit for an individual.